AMENDMENTS TO THE DRAWINGS

Please cancel Figure 5 and substitute the Replacement Sheet submitted herewith.

REMARKS

Status Summary

Claims 150 – 152, 158 – 164, 167 – 174, 181 – 187, 190 – 210, 213 – 221, 227 – 233, and 236 – 251 are pending. Claims 200 – 203 and 244 – 247 are presently amended. Claims 1 – 149, 153 – 157, 165, 166, 175 – 180, 188, 189 211, 212, 222 – 226, 234, 235 and 252 – 268 are cancelled. Claims 269 – 290 are newly added.

Claims 269 and 272 specify that the monomeric cytotoxic drug derivative/anti–CD22 antibody conjugates set forth in claims 150 and 196 (respectively) have the formula shown in Figure 17. Claims 270 and 273 specify that the anti-CD22 antibody of claims 269 and 272 (respectively) are expressed in a mammalian cell prior to being conjugated to the cytotoxic drug and comprise a light chain comprising residues 21 to 239 of SEQ ID NO: 28 and a heavy chain comprising residues 20 to 466 of SEQ ID NO: 30. Claims 271 and 274 specify that the anti-CD22 antibody of claims 269 and 272 (respectively) comprise a light chain consisting of an amino acid sequence resulting from the expression of SEQ ID NO: 29 in a mammalian cell and a heavy chain consisting of an amino acid sequence resulting from the expression of SEQ ID NO: 31 in a mammalian cell. As one of ordinary skill in the art would readily appreciate, antibodies comprise sequences that are removed during post-translational processing of the antibody in mammalian cells and consensus cleavage sites and motifs were known in the art at the time of filing (*see e.g.*, Specification, page 44, lines 8 – 17; page 45, lines 19 – 25; SEQ ID NOs: 19, 27, 31 and 51; Figure 16; and Kabat et al., *Sequences of Proteins of Immunological Interest*, 5th Edition, 1991).

Claims 275 – 278 specify that the leukemia described in claims 164, 187, 210 and 233 (respectively) is acute lymphocytic leukemia (ALL). Support for these claims may be found in the specification at least at p. 40, lines 8 – 21.

Claims 279 – 290 specify particular dosage regimens for administration of particular monomeric cytotoxic drug derivative/anti–CD22 antibody conjugates described in antecedent claims. Support for these claims may be found in the specification at least at p. 36, lines 15 – 22.

The specification is objected to. The amendments to the claims submitted on 8 March 2010 are objected to under 37 C.F.R. §1.121(c). Figure 5 is objected to. Claims 200 – 203 and 244 – 247 are rejected as allegedly failing to meet the enablement requirement of 35 U.S.C. § 112, first paragraph. Claims 150 – 152, 158 – 164, 150 – 152, 158 – 164, 167 – 174, 181 – 187,

190 – 210, 213 – 221, 227 – 233, and 236 – 251 are provisionally rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 210 – 214 of co-pending U.S. Patent Application No. 10/428,894 ("Kunz") in view of Tsai et al., *Clin. Lymphoma*. 2000 Jun:1(1):62-66 ("Tsai") and in further view of Press et al., *Hematology Am. Soc. Hematol. Educ. Program*, 2001:221-40 ("Press").

No new matter is added by the amendments herein. Reconsideration is respectfully requested in view of the aforementioned amendments and following remarks.

Rejections of Claims Under 35 U.S.C. §112, first paragraph (enablement)

In item 5 of the official action, claims 200 – 203 and 244 – 247 are rejected as allegedly failing to meet the enablement requirement of 35 U.S.C. § 112, first paragraph. Specifically, the examiner alleges that does not reasonably provide enablement for anti-CD22 antibodies comprising a heavy chain framework residue selected from one or more of positions 1, 28, 48, 72, and 97 (linear numbering) of SEQ ID NO:8 occupied by Glu, Arg, Ile, Ala, and Thr, respectively, wherein the remainder of the heavy chain framework is occupied by corresponding residues of the human acceptor framework of SEQ ID NO: 21 or 22 or an anti-CD22 antibody comprising a light chain framework residue selected from one or more of positions 2, 4, 42, 43, 50, and 65 (linear numbering) of SEQ ID NO:7 occupied by Val, Val, Leu, His, Gln, and Asp, respectively, wherein the remainder of the light chain framework is occupied by corresponding residues of the human acceptor framework of SEQ ID NO: 17 or 18 (i.e., antibodies comprising partial human framework regions). Official action, pp. 7 – 10.

In response, claims 200 – 203 and 244 – 247 are amended to specify that the anti–CD22 antibody comprises a light//heavy chain framework residue selected from one or more of residues in SEQ ID NO: 7//8, wherein the remainder of the light/heavy chain framework region is occupied by corresponding residues of the human acceptor framework of SEQ ID NO: 17 *and* 18 //21 *and* 22 (i.e., a complete human acceptor framework). Accordingly, withdrawal of the rejections of claims 200 – 203 and 244 – 247 under 35 U.S.C. § 112, first paragraph is respectfully requested.

Provisional Rejection of Claims under the Judicially Created Doctrine of Obviousness-Type Double Patenting

In item 6 of the official action, claims 150 – 152, 158 – 164, 150 – 152, 158 – 164, 167 – 174, 181 – 187, 190 – 210, 213 – 221, 227 – 233, and 236 – 251 are provisionally rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 210 – 214 of co-pending U.S. Patent Application No. 10/428,894 ("Kunz") in view of Tsai et al., *Clin. Lymphoma*. 2000 Jun:1(1):62-66 ("Tsai") and in further view of Press et al., *Hematology Am. Soc. Hematol. Educ. Program*, 2001:221-40 ("Press"). Specifically, the examiner alleges that although the claims are not identical to those of Kunz, Kunz discloses N-acetyl-gamma calicheamicin DMH-anti-CD22 antibody conjugates having amino acid sequences that are identical to those in the instant claims. The examiner also alleges that Tsai teaches a method of treating B-cell malignancy patients using CHOP, rituximab and anti-CD22, and Press teaches the combination of Rituximab with chemotherapy (CHOP, DHAP, CVP) in B-cell malignancy, as well as intravenous administration of rituximab. Official action, pp. 11 – 12.

In response, the applicants submit herewith a terminal disclaimer over commonly owned U.S. Patent Application No. 10/428,894 in compliance with 37 C.F.R. §1.321(c). Accordingly, withdrawal of the provisional rejections of claims 150 – 152, 158 – 164, 150 – 152, 158 – 164, 167 – 174, 181 – 187, 190 – 210, 213 – 221, 227 – 233, and 236 – 251 under under the judicially created doctrine of nonstatutory obviousness-type double patenting is respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that claims 150 – 152, 158 – 164, 150 – 152, 158 – 164, 167 – 174, 181 – 187, 190 – 210, 213 – 221, 227 – 233, 236 – 251, and 269 – 290 are in condition for allowance and a notice to that effect is earnestly solicited. If any points remain in issue, which may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,
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